

### **REMARKS**

Claims 1-21 and 24-53 are currently pending and stand rejected. Applicants respectfully request reconsideration in view of the following amendments and remarks.

#### ***Claim Amendments***

Applicants amend claims 24, 34, and 53 to recite that first and second members are positioned on the same central longitudinal axis. Support for this amendment can be found throughout the specification and in the drawings, for example at page 36, lines 17-28 of the application. No new matter is added.

#### ***Claim Rejections Pursuant to 35 U.S.C. §102***

##### **Wilk**

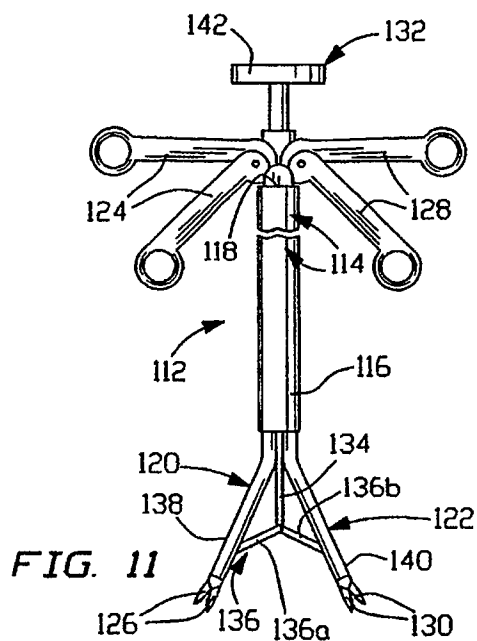
Claims 1-3, 45, and 49-51 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,395,367 of Wilk. The Examiner also rejects claims 5-7, 9, 17, 18, and 20 pursuant to 35 U.S.C. §102(b) as being anticipated by, or in the alternative, pursuant to 35 U.S.C. §103(a) as being obvious over Wilk.

##### **Independent Claim 1**

Independent claim 1 recites a tissue shaping instrument having a first tissue engaging device and a second tissue engaging device, with said second tissue engaging device being hingedly pivotable relative to a long-axis of the elongated member. The Examiner refers to FIGS. 10-12C of Wilk as allegedly teaching the claimed second tissue engaging device that is “hingedly pivotable” relative to a long-axis of the elongated member. The Examiner states that “the pivot between 136a or 136b and 134 and/or between 136a and 138 or between 136b and 140” meets the requirements of claim 1. *Office Action dated May 11, 2009, page 2.*

At the outset, there is not a single mention in all of the Wilk reference of a “hinge” or of some portion of the device of Wilk being “hingedly” pivotable relative to another portion. The figures, such as FIG. 11 which is reproduced herein, and the passage of Wilk that the Examiner refers to, simply teaches that a push rod 132 is “pivotably” connected with arms 136a, 136b, and

that the arms 136a, 136b are “pivotably” connected to grasping forceps 120, 122 (i.e., tissue engaging devices). There is no mention of a hinge or of the arms 136a, 136b being “hingedly” connected to anything.



In addition, the grasping forceps 120, 122 are not even pivotable relative to the long axis of the device, as required by claim 1, but instead are bendable relative to the long axis. The pivot points that are a part of the push rod 132 have nothing to do with the forceps 120, 122, other than to cause movement of the forceps. Wilk teaches that the shafts 138, 140 of the grasping forceps 120, 122 are “flexible in a region immediately distal of a distal end of the frame member 114...thereby enabling a relative

spreading of grasping forceps 120, 122 from a straightened...configuration...” *Wilk, col. 11, line 68 – col. 12, line 5*. It is also noteworthy that shafts 138, 140 are solid continuous members, making it impossible for them to be hinged or hingedly pivotable. Claim 1 clearly requires that the second tissue engaging device be hingedly pivotable relative to a long axis of the device. Wilk fails to teach or suggest a tissue engaging device that is pivotable at all and does not teach any component, much less a tissue engaging device, that includes a hinge that would enable it to be hingedly pivotable. Wilk simply cannot anticipate claim 1. For all of these reasons, claim 1, as well as claims 2, 3, 45, and 49-51 which depend therefrom, distinguish over Wilk and represent allowable subject matter.

#### Independent Claim 5

Independent claim 5 recites an elongated member having an inner tubular member and an

outer tubular member concentrically disposed around the inner tubular member. A first tissue engaging device is disposed on one of the inner and the outer tubular member and a second tissue engaging device is disposed on one of the inner and the outer tubular member.

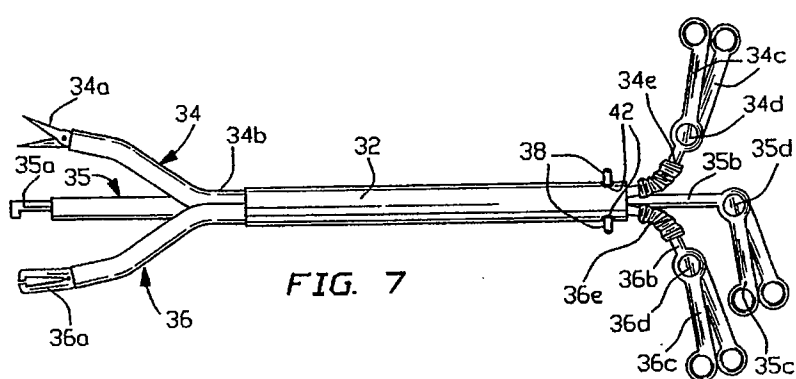
In the rejection and in the Response to Arguments of the Office Action dated May 11, 2009, the Examiner suggests multiple interpretations as to how Wilk meets the requirements of claim 1. If these interpretations are examined together, however, it becomes clear that Wilk cannot actually meet all of the requirements of claim 1. Applicants therefore outline these interpretations and their failures below.

In one interpretation, the Examiner states that Wilk teaches “an elongated member having an inner tubular member (e.g., sheath of 35 or 36) and an outer tubular member (32) concentrically disposed around the inner tubular member.” *Office Action dated May 11, 2009, page 5.* Regarding this rejection, in his Response to Arguments, the Examiner gives the definition of “concentric” and argues that he is giving the term its “broadest reasonable interpretation.”

The first definition of concentric that the Examiner puts forth is: “with common middle point: describes circles and spheres of different sizes with the same middle point.” The second definition is: “with common axis: with common axis or center line.” *Id.*

*at 12.* The Examiner uses FIG. 7 of Wilk, which is reproduced herein, to illustrate the “broadest reasonable interpretation” that he is giving to Wilk. With regard to the first definition, the Examiner states that

“the sheaths of elements 34, 35, and 36 can be said to share a common middle point with element 32. That is, a middle point between the axes of the sheaths (inner tubular member) is common with the axis of element 32 (outer tubular member).” *Id., page 12.* This is simply wrong. Each of the three circular shafts 34, 35, and 36 have their own middle point that is different from one another



and offset from the middle point of the sheath 32. The middle points of the shafts 34, 35, and 36 are not common with the middle point of the sheath 32, as the definition requires. The Examiner's statement that "a middle point between the axes is common with the axis of element 32" has nothing to do with the definition of "concentric." In sum, the three shafts 34, 35, 36 extending through the sheath 32 cannot meet the requirement that the outer tubular member be disposed concentrically around the inner tubular member.

With regard to the second definition and under the Examiner's second interpretation, the Examiner states that "element 144 (outer tubular member in this case) can be said to have a common axis with element 32 (the inner tubular member in this case)." *Id. at 13*. This too is plainly wrong. First, element 144 is never taught by Wilk as being usable with sheath 32. Regardless, even if they are used together in the way the Examiner suggests, neither the element 144 nor the sheath 32 has a tissue engaging device disposed thereon, as also required by claim 5. In particular, claim 5 requires that the first and second tissue engaging devices be disposed on one of the inner and the outer tubular member. The shafts 34, 35, and 36 could never be disposed on either the element 144 or the sheath 32 because they must be capable of moving freely within and through the sheath 32, as explained in more detail below. Accordingly, under this second interpretation, Wilk still cannot meet all of the requirements of claim 5.

With regard to another aspect of claim 5, the Examiner states that the shafts 34, 35, and 36 are in contact with one another and thus meet the requirement of claim 5 that the first and second tissue engaging devices be disposed on the inner tubular member. Although it is not clear, Applicants believe the Examiner is saying that any of the shafts 34, 35, and 36 can be the claimed inner tube and any of the other shafts can be a tissue engaging device "disposed on" the inner tube because they contact one another. Although Applicants disagree with this interpretation of "disposed on," Wilk still cannot meet the other requirements of the claim. In particular, under this interpretation, the outer tube (sheath 32) is not disposed concentrically around the inner tube (i.e., one of the shafts 34, 35, 36) for all of the reasons noted above.

Finally, in an alternate rejection of claim 5 pursuant to 35 U.S.C. §103(a), the Examiner

appears to admit that the only configuration of Wilk that meets the “concentric” requirement of claim 5 is the device of FIG. 4 and/or of FIGS. 12A-12C in which the tissue manipulation instrument is placed through a cannula or other outer tube. The Examiner then admits that these devices do not have tissue engaging devices disposed on one of the inner and the outer tube. But the Examiner says it would be obvious “to dispose the first and second tissue engaging devices on the proximal surface of one of the inner tubular member and the outer tubular member. Such a configuration would safely prevent the engaging devices from being inserted too far or dropped through a tubular member, and it would allow the actuators of the engaging devices to remain outside of a patient’s body for convenient access to the devices by a user.” *Office Action dated May 11, 2009, page 7.*

Applicants strongly disagree that this proposed modification would have been obvious to one skilled in the art, as it would completely destroy the purpose and function of the device of Wilk. The Background of Wilk explains the problem it is attempting to solve. Wilk states that “[i]t frequently occurs during laparoscopic surgery that an additional instrument is temporarily required. Inserting this extra instrument has usually involved either temporarily removing one of the other instruments or forming another perforation with a trocar.” *Wilk, col. 1, lines 62-66.* Wilk then discloses a device in which multiple tubular members can be inserted through a sleeve for ease of manipulation and adjustment. It teaches that the tubular members are designed to be slidably disposed within the sleeve to move between retracted and extended positions and that the instruments are intended to be selectively replaced with different actuators as needed. In fact, Wilk states that the “handles are preferably locked in some way to the instrument shafts” for easier replacement. *Wilk, col. 3, lines 5-40.* Modifying Wilk to dispose the proximal portions of the instruments (i.e., the handles) on the proximal portion of the inner or outer tube would completely remove the ability of the instruments to be slidable relative to the sheath and to be selectively replaced as needed. This is the fundamental solution to the problem Wilk was attempting to solve, and the Examiner’s proposed modification would destroy the solution.

In addition, the reasoning that the Examiner gives for such a modification is also faulty. The Examiner claims that the modification would essentially prevent the instruments from being

inserted too far or from being dropped through the tubular member. A simple glance at any of the figures of Wilk, however, clearly shows that the handle portions of the instruments have been designed to be much too large to “drop” through the sheath or cannula even in a vertical orientation. It would be impossible for them to do so. Furthermore, the fact that the handles of the instruments have additionally been designed to be used in an angular or horizontal orientation relative to the tubular member illustrates the further impossibility of such an occurrence. The Examiner’s proposed modification of Wilk simply would not have been obvious to one skilled in the art.

For all of these many reasons, claim 5 distinguishes over Wilk and represents allowable subject matter.

**Yoon**

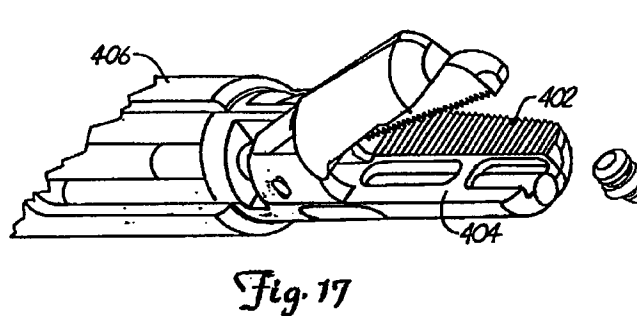
The Examiner rejects claims 24, 25, 27, 29-34, and 53 pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,954,731 of Yoon.

Independent claims 24, 34, and 53 all require first and second members that are positioned on the same central longitudinal axis. Yoon is directed to a device having a single channel through which various tissue engaging members can be disposed in parallel. Each of the tissue engaging members of Yoon is positioned on a central longitudinal axis (i.e., a straight line extending through the center of the member along its long-axis) that is parallel with the central longitudinal axes of the other tissue engaging members and with the central longitudinal axis of the elongate member through which it is disposed. None of the tissue engaging members, however, are positioned on the same central longitudinal axis since there is never a case where the center line of one tissue engaging member is the same as the center line of another tissue engaging member. The tissue engaging members of Yoon can only extend through the parallel channels of the elongate member and will thus never be positioned on the same central longitudinal axis as another tissue engaging member. Accordingly, claims 24, 34, and 53, as well as claims 25, 27, and 29-33 which depend therefrom, distinguish over Wilk and represent allowable subject matter.

**Kuehn**

Claims 34, 35, 37, and 39-44 are rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,695,866 of Kuehn et al. ("Kuehn").

Independent claim 34, as amended, requires an elongated member having first and second movable members positioned on the same longitudinal axis. The Examiner refers to the jaws 404 of Kuehn, shown in FIG. 17 which is reproduced herein, as the first and second movable members and then states that "element 404 can be 'withdrawn' while element 402 grabs tissue." *Office Action dated May 11, 2008, page 4*. Applicants are thus unsure whether the jaws 404 are being considered the first and second movable members or whether jaws 404 and jaws 402 are being considered the first and second movable members. Either way, neither interpretation can meet the requirements of claim 34. All four components (the two jaws 404 and the two jaws 402) are positioned on different central longitudinal axes. The jaws 404 and 402 are positioned in parallel with one another and the jaw members are pivotably connected to one another. Thus, each of the components is positioned on a different central longitudinal axis that will never be the same as any one of the others. Accordingly, claim 34 as well as claims 35, 37, and 39-44 which depend therefrom, distinguish over Kuehn and represent allowable subject matter.



***Claim Rejections Pursuant to 35 U.S.C. §103***

**Wilk and McGarry**

Claims 4, 10-13, and 21 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,289,963 of McGarry et al. ("McGarry"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in these claims. Thus, the Examiner relies on McGarry to

disclose these limitations. McGarry is directed to a surgical stapler having a single stapling device at one end of an elongate member. McGarry, however, fails to remedy the deficiencies of Wilk with regard to independent claims 1 and 5, from which claims 4, 10-13, and 21 depend. In particular, McGarry does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member. In addition, McGarry does not teach or suggest an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claims 4, 10-13, and 21 distinguish over the combination of Wilk and McGarry at least because they depend from an allowable base claim.

Wilk and McPherson

Claims 8 and 52 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,437,266 of McPherson et al. ("McPherson"). Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in these claims. Thus, the Examiner relies on McPherson to disclose these limitations. McPherson is directed to a surgical retractor having a coiled screw at one end of the device. McPherson, however, fails to remedy the deficiencies of Wilk with regard to independent claims 1 and 5, from which claims 8, 26, 36, 38, and 52 depend. In particular, McPherson does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member. In addition, McPherson does not teach or suggest an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claims 8 and 52 distinguish over the combination of Wilk and McPherson at least because they depend from an allowable base claim.



Yoon and McPherson

Claim 26 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Yoon in view of McPherson. Applicants respectfully disagree.

The Examiner states that Yoon discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in claim 26. Thus, the Examiner relies on McPherson to disclose these limitations. McPherson is directed to a surgical retractor having a coiled screw at one end of the device. McPherson, however, fails to remedy the deficiencies of Yoon with regard to independent claim 24 from which claim 26 depends. In particular, McPherson does not teach or suggest first and second members disposed on the same central longitudinal axis, as required by claim 24. Accordingly, claim 26 distinguishes over Yoon in view of McPherson at least because it depends from an allowable base claim.

Wilk and McPherson

Claim 36 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of McPherson. Applicants believe this rejection is incorrect since claim 34, from which claim 36 depends, was not rejected over Wilk. Applicants thus assume this claim is allowable.

Wilk and Kuehn

Claim 14 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kuehn. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose at least one tissue fixation device that is a two-part fastener. Thus, the Examiner relies on Kuehn to disclose such a tissue fixation device. As noted above, Kuehn is directed to a device for mitral and tricuspid valve repair and fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 14 depends. In particular, Kuehn does not teach or suggest an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and first and second tissue engaging devices each

disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claim 14 distinguishes over the combination of Wilk and Kuehn at least because it depends from an allowable base claim.

*Wilk and Kammerer*

Claims 15 and 16 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of Kammerer. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 15 and 16. Thus, the Examiner relies on Kammerer to disclose these limitations. Kammerer is directed to an H-type fastener for tissue. Kammerer, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claims 15 and 16 depend. In particular, Kammerer does not teach or suggest an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claims 15 and 16 distinguish over the combination of Wilk and Kammerer at least because they depend from an allowable base claim.

*Wilk and Yoon*

Claim 19 is rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,954,731 of Yoon. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose a viewing endoscope. Thus, the Examiner relies on Yoon to disclose such an endoscope. Yoon is directed to a surgical instrument with multiple rotatably mounted spreadable end effectors. Yoon, however, fails to remedy the deficiencies of Wilk with regard to independent claim 5, from which claim 19 depends. In particular, Yoon does not teach or suggest an elongated member having an inner tubular member and an outer tubular member concentrically disposed around the inner tubular member and first and second tissue engaging devices each disposed on one of the inner and the outer tubular member, as required by claim 5. Accordingly, claim 19 distinguishes over the

combination of Wilk and Yoon at least because it depends from an allowable base claim.

Yoon and Wilk

Claims 28 and 38 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Yoon in view of Wilk. Applicants respectfully disagree.

The Examiner states that Yoon discloses the invention substantially as claimed, but fails to disclose certain limitations as recited in these claims. Thus, the Examiner relies on Wilk to disclose these limitations. Wilk, however, fails to remedy the deficiencies of Yoon with regard to independent claims 24 and 34, from which claims 28 and 38 depend. In particular, Wilk does not teach or suggest first and second members disposed on the same central longitudinal axis, as required by claim 24. Accordingly, claims 28 and 38 distinguish over Yoon in view of Wilk at least because they depend from an allowable base claim.

Wilk and Iacovelli

Claims 46-48 are rejected pursuant to 35 U.S.C. 103(a) as being obvious over Wilk in view of U.S. Patent No. 5,350,391 of Iacovelli. Applicants respectfully disagree.

The Examiner states that Wilk discloses the invention substantially as claimed, but fails to disclose the limitations of claims 46-48. Thus, the Examiner relies on Iacovelli to disclose these limitations. Iacovelli is directed to a laparoscopic scissors device but fails to remedy the deficiencies of Wilk with regard to independent claim 1, from which claims 46-48 depend. In particular, Iacovelli does not teach or suggest a tissue engaging device that is hingedly pivotable relative to a long-axis of an elongated member, as required by claim 1. Accordingly, claims 46-48 distinguish over the combination of Wilk and Iacovelli at least because they depend from an allowable base claim.

***Conclusion***

In view of the above remarks, Applicants submit that all claims are in condition for allowance, and allowance thereof is respectfully requested.

Respectfully submitted,

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